

REMARKS

Reconsideration is requested.

Claims 65-77 are pending. Support for claim 77 may be found throughout the specification as originally filed. No new matter has been added.

Return of an initialed copy of the attached PTO-1449 Form, as an indication that the references listed therein have been considered by the Examiner, pursuant to MPEP §609, is requested. Copies of the cited references are attached except for the cited Nishihara and Ralston journal references which are of record in the parent U.S. Patent 6,150,134 and should be separately available to the Examiner. The parent patent was cited to the Examiner in the Information Disclosure Statement filed May 22, 2001, and return of an initialed copy of the PTO-1449 Form, listing the same, pursuant to MPEP §609, is requested. The Examiner is also requested to return an initialed copy of the PTO-1449 Form, filed with the Information Disclosure Statement of September 11, 2002.

The Section 112, first paragraph, rejection of claim 66 is, to the extent not obviated by the above, traversed. Reconsideration and withdrawal of the rejection are requested in view of the following comments.

Synthesis of the peptides is referred to in Example 7.3, page 54, lines 17-18 of the application. Moreover, for at least for peptides defined by SEQ ID NOs:53, 72, 73, 82, 83, 68, 87, 88, a working example is provided for their usefulness in detection of anti-E1 or anti-E2 antibodies (see page 55, lines 20-34 and page 56, lines 25-34). The peptides of

the invention thus can be made and used, also in specific rather than generic molecular assays. Withdrawal of the Section 112 rejection of claim 66 is requested.

The Section 112, second paragraph, rejection of claims 65-76 is obviated by the above amendments. Reconsideration and withdrawal of the Section 112, second paragraph, rejection are requested.

The Section 102 rejection of claims 65 and 67-73 over Choo (PNAS (1994) Volume 91:1294-1298), is traversed. Similarly, the Section 102 rejection of claims 65 and 67 and 73 over Ralston (U.S. Patent No. 6,274,148), is traversed. Reconsideration and withdrawal of the Section 102 rejections are requested in view of the following distinguishing comments. The Examiner is asserting that claims 65 and 67-73, and more specifically E1 or E2 proteins being at least 80% pure, are anticipated by Choo et al. (1994) (PNAS 91, 1294-1298) under 102 (a) and by Ralston (U.S. 6,274,148) under 102 (e).

U.S. Patent No. 6,274,148 (Ralston) is a continuation-in-part of co-pending U.S. Serial No. 07/758,880, filed September 13, 1991, which is a continuation-in-part of U.S. Serial No. 07/611,419, filed November 8, 1990, now abandoned.

The Examiner is urged to review Ralston et al. (1993) (J. Virol. 67, 6753-6761), which was published after filing of the parental Ralston (application U.S. 07/758,880). In the abstract of Ralston et al. (1993) (J. Virol. 67, 6753-6761) it is stated that "E1 and E2 were copurified to approximately 90% purity...". The term "copurified" is significant as E1 and E2 were co-expressed and are forming E1-E2 complexes. The complexation of E1 and E2 necessarily makes it impossible to purify single E1 and single E2 proteins

(unless additional steps such as outlined in the current invention are inserted in the purification procedure). Furthermore, this E1/E2 complex was used to immunize chimpanzees as described in by Choo et al. (1994) (PNAS 91, 1294-1298), the paper being referred to in the abstract of Ralston et al. (1993) (J. Virol. 67, 6753-6761).

The Examiner is further urged to review U.S. 2002/0004048 (Ralston) (attached) which is a continuation-in-part of copending U.S. Serial No. 07/758,880 filed September 13, 1991, which is a continuation-in-part of U.S. Serial No. 07/611,419, filed November 8, 1990, now abandoned. The Examiner is requested to see claims 36-39 therein which are covering a HCV asialoglycoprotein composition comprising a purified HCV E1/E2 asialoglycoprotein aggregate (claim 36) which is at least 40% (claim 37), 50% (claim 38) or 60% (claim 39) pure. Thus, complexes of at least 80% purity are not claimed. This despite earlier publications mentioning complexes which are 80-90% pure. The currently claimed invention however provides purified recombinant HCV single or specifically oligomerized envelope proteins to a degree of at least 80% purity (and up to 90%, 95%, 97%, 98%, 99% purity). This is reflected in claims 18-26 of the granted parental U.S. case, 6,150,134 of this invention. As a matter of fact, comparative experimentation (submitted by Declaration to U.S. 6,150,134) has indicated that the procedure as outlined in e.g. Ralston (U.S. 6,274,148) leads to HCV envelope proteins of less than 80% pure while the purification procedure of the present invention leads to HCV envelope proteins that are more than 90% pure. Further evidence of the same should not be required.

Overall, it is submitted that claims 65 and 67-73 are not anticipated by Choo et al. (1994) (PNAS 91,1 294-1298), nor by Ralston (U.S. 6,274,148) as these fail to teach the presently claimed invention.

Reconsideration and withdrawal of the Section 102 rejections are requested.

The Section 102 rejections of claim 66 over WO 9318054, U.S. Patent No. 5,747,239, U.S. Patent No. 6,183,949, WO 9306247, and WO 9364205, are traversed. Reconsideration and withdrawal of the rejections are requested as none of the cited art provides the specifically claimed peptides.

The Examiner is requested to hold in abeyance the obviousness-type of double-patenting rejection of claim 65-74 over claims 1-5, 8-17 and 21 of U.S. Patent No. 6,150,134, until such time as patentable subject matter is identified. The applicants will then consider whether to file a Terminal Disclaimer in response to any further double-patenting rejection.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested. The Examiner is requested to contact the undersigned if anything further is required in this regard.

Respectfully submitted,

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By: \_\_\_\_\_



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